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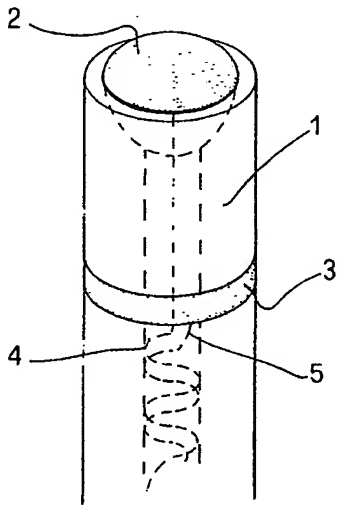
(54) **Intracardiac catheter, magneto-cardiographically localizable, for mapping and pacing provided with means for ablation of arrythmogenic tissue.**

(57) A catheter (1) for intracardiac mapping, pacing biopsy and ablation of arrythmogenic tissue, comprises at its tip two non-polarizable, non-ferromagnetic electrodes (2, 3), arranged in such a way that an electromagnetic field of dipolar configuration can be generated in the heart by connecting them to an external current generator. The connection is done with twisted pairs of non-ferromagnetic conductors (4, 5) to avoid any other magnetic field along the catheter during cardiac pacing. With this assembly the tip of the catheter can be localized (and driven close to an arrhythmogenic target) by using the magnetocardiographic mapping method for three-dimensional localization and imaging. The catheter can be made of different kinds of non-thrombogenic, flexible, insulated, sterilizable material, with multiple parallel lumens (6..8; 9, 10) to allow fluid infusion, suction and/or introduction of ablation or biopsy devices.

FIG 1



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MAGNETICALLY LOCALIZABLE MULTIPURPOSE CATHETER FOR MAGNETOCARDIOGRAPHIC GUIDED INTRACARDIAC MAPPING, BIOPSY AND ABLATION OF CARDIAC ARRHYTHMIAS.

The subject matter of the present invention consists of a specially designed multilumen electrocatheter which, for its configuration and materials, can be localized and driven close to an arrhythmogenic target in connection with the magnetocardioagraphic mapping and localization technique. The catheter itself can be used as a guide for ablation and/or biopsy devices, for fluid infusion and to apply suction.

During the last twenty years, the electrogenetic mechanism of cardiac arrhythmias has been widely investigated at clinical level by combining direct recording of endocardial electrograms and programmable electrical stimulation of the heart.

For both endocardial recording and pacing, commercially available electrocatheters are usually reliable, provided that a recording bandwidth of 30/50-1000 Hz is used. In particular high pass filters are mandatory to obtain stable recordings and avoid offset phenomena due to biological low frequency components (such as respiration) or to polarization of the electrodes during recording and pacing. Filtered signals are reliable for timing of local endocardial activation, but inadequate for the study of transient variation of specific electrophysiological parameters. On the contrary, the recording of monophasic action potential (MAP), a signal which must be typically recorded in open bandwidth (DC to 1 KHz), is gaining a growing interest for the beat-to-beat study of cardiac repolarization and of diastolic arrhythmogenic phenomena under different pathophysiological conditions. At present for MAP recordings, in order to minimize polarization phenomena, electrocatheters with Ag/AgCl electrodes are used which however polarize if used for pacing. It is evident therefore that it would be impossible to employ the same electrocatheter for monophasic action potential recording and endocardial pacing. On the other hand, MAP recordings have to be carried out in close proximity to the arrhythmogenic areas when diastolic phenomena, such as afterpotentials, have to be identified. A method is needed therefore to drive a mapping catheter, as well as biopsy and/or ablation devices, right onto the arrhythmogenic zone.

Catheter positioning and localization are usually carried out under fluoroscopic control, with a spatial resolution which is sufficient for routine electrophysiological evaluations, but sometimes inadequate for an accurate three-dimensional localization of arrhythmogenic foci, which is the prerequisite for successful surgical or catheter ablation of arrhythmias. The precision of catheter positioning can be moderately improved by measuring the "local activation time" on the electrograms recorded by the catheter in respect of a fixed reference lead, and taking into account the morphology of the signals.

In order to improve the pre-surgery localization of arrhythmogenic structures, different intracardiac mapping methods have been developed, which imply the use of multielectrode catheters. The spatial localization accuracy of such invasive methods has not been precisely quantified so far. Its average uncertainty is estimated in the order of 1.5-2 cm in the three dimensions.

In patients who undergo open chest surgical ablation of arrhythmias, it is usually possible to verify the preoperative localization accuracy by intraoperative epicardial mapping. On the contrary when catheter ablation is the procedure chosen, the success is only dependent on:

a) The accuracy of catheter mapping to localize the arrhythmogenic area.

b) The capability to drive the ablation catheter right onto (or as close as possible to) the target arrhythmogenic tissue.

The latter point is obviously more critical when extremely focused ablation energies (i.e. laser, radiofrequency or thermal ablation) are chosen, which determine lesion of only a few millimeters. Catheter positioning reproducibility is extremely important taking into acccount that in some cases multiple sessions are needed for complete ablation of the arrhythmogenic tissue.

Within the finalized research project on "Biomagnetism" of the Italian National Research Council, a magnetocardiographic method has been developed, in the Cardiovascular Biomagnetism Unit of the Catholic University of Rome, which allows the non-invasive three-dimensional localization of arrhythmogenic cardiac tissue with a spatial resolution which is at least comparable to that obtainable with the conventional invasive techniques. Moreover, using a prototype of this invented catheter, it has been demonstrated that the tip of the catheter could be three-dimensionally localized within the patient's cardiac volume, by magnetocardiographic mapping performed while pacing the heart with the specially designed distal electrodes.

On the contrary, standard commercially available pacing electrocatheters are not magnetically localizable because of ferromagnetic induced artifacts and/or improper magnetic field pattern generation. On the other hand electrocatheters with Ag/AgCl electrodes are not feasible for cardiac

pacing and therefore not localizable by magnetic mapping.

The multipurpose electrocatheter according to the present invention allows:

1) biomagnetic localization of the tip of the catheter,

2) monophasic action potential and standard electrograms recording,

3) endocardial pacing.

The multipurpose cardiac electrocatheter of the invention comprises at least two non-ferromagnetic non-polarizable electrodes shaped in such a way as to generate an electric field of dipolar configuration, the two electrodes being connected to the external pacing devices through a pair of copper insulated wires, twisted all along the catheter length up to the electrodes, in order to guarantee absence of magnetic field along the catheter during pacing, the catheter itself being a flexible cylindrical tube of plastic material fully electrically insulated except where the distal and proximal electrodes are placed. The catheter itself is of biocompatible, non-thrombogenic, thin wall plastic material with sufficient torque resistance and pushability.

The cardiac electrocatheter can be provided, besides the lumen for the electrode wires, with other multiple parallel lumens, with terminal and/or lateral eyelets, to insert ablation wires or fiberoptics, to apply suction, intracardiac pressure measurements and fluid infusion.

In a specific embodiment of the invention the distal electrode can be hemispherically shaped and the proximal electrode can be ring-shaped.

In another embodiment both the distal and proximal electrodes can be ring-shaped.

The equivalent surface of the electrodes in the cardiac electrocatheter of the invention ranges between 5 and 15 mm^2.

The interelectrode distance ranges between 2 and 7 mm.

The material used for the electrodes is preferably selected from the group comprising platinated platinum and amorphous carbon.

The internal wires are insulated pure copper twisted pairs (diameter about 200 µm). Such a material should be appropriately worked to be flexible and torque resistant.

The catheter tube material is preferabaly selected from the group comprising polyurethan, polyethylenterephtalate, polyethylene or polyvinylchloride.

The size of the catheter can range between 1.67 and 2.60 mm (5 and 8 F, F meaning French).

The catheter according to the present invention can be used for:

A) Conventional (filtered) intracardiac mapping.

B) Intracardiac mapping of monophasic action potentials.

C) Calibration of biomagnetic systems for accuracy of cardiac sources localization.

D) Biomagnetic localization of the catheter tip position with respect to the site of origin of cardiac arrhythmias, previously localized by magnetocardiographic mapping.

E) An integrated system for biomagnetically driven intracardiac catheter ablation of arrhythmogenic tissue and/or endomyocardial biopsy.

After the general description of this multipurpose catheter, a more detailed explanation is now given of possible variants for special applications in connection with biomagnetic imaging.

Figure 1 shows a perspective view of the catheter tip (dashed lines indicate the internal parts) in the simplest configuration;

Figure 2 shows a perspective view of the catheter tip in the multilumen configuration which features one central and two parallel lateral lumens (eyelets can be lateral and/or at the tip of the catheter); and

Figure 3 shows a perspective view of the catheter tip in a configuration which features only two parallel lumens, with tip or lateral eyelets.

In figure 1, the catheter wall in polyurethan is indicated by 1. The distal (tip) hemispheric electrode 2, and the proximal (ring) electrode 3 are both made of platinated platinum. 4 and 5 are the internal copper wires (diameter: 200 µm) distally connected to the distal electrode 2 and to the proximal electrode 3 respectively. The electrodes' equivalent surface is 7 square millimeters. The interelectrode distance is 5 mm. The external catheter size is 5 F (1.67 mm).

In figure 2, a different configuration of the catheter is shown which features a central lumen 6 (diameter = 0.035 inches, i.e. 0.889 mm) and two thinner lateral lumens 7 and 8, available to introduce fiberoptics or ablation wires, apply suction or fluid infusion. The central lumen implies the anular configuration of the distal electrode 2, while the proximal electrode 3 is unchanged. In figure 3, a third catheter configuration is shown, which features only two lateral lumens 9 and 10, available for ablation wires and/or fiberoptics introduction.

The biomagnetic driving technique of the ablation catheter on the arrhythmogenic target comprises the following steps:

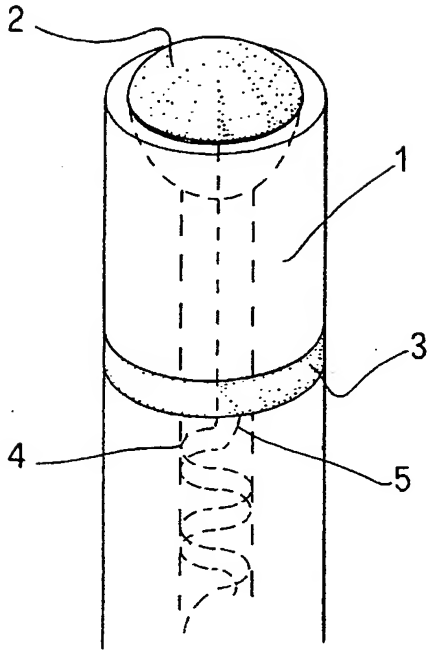
- one or more preliminary magnetocardiographic studies of the patient are performed to identify the reproducibility of the magnetic field distribution generated by the arrhythmogenic structures to be ablated, the three-dimensional localization of the arrhythmogenic area being obtained by inverse solution with the equivalent current dipole or current multipole expansion models;
- on the basis of this and other conventional localization procedures the biomagnetically drivable

ablation catheter is placed, under fluoroscopic control, as close as possible to the target zone; - a magnetocardioagraphic mapping is performed during cardiac pacing through the catheter artificial dipole (electrodes 2 and 3); and
- the catheter position is reliable for ablation when the paced field fits at the best the magnetic field distribution generated by the arrhythmogenic structure, or accepted as representative of the site of origin of the arrhythmia to be treated.

Claims

1. A multipurpose cardiac electrocatheter, which comprises at least two non-ferromagnetic non-polarizable electrodes shaped in such a way as to generate an electric field of dipolar configuration, the two electrodes being connected to the external pacing devices through a pair of copper insulated wires, twisted all along the catheter length up to the electrodes, in order to guarantee absence of magnetic field along the catheter during pacing, and the catheter itself being a flexible cylindrical tube of plastic material fully electrically insulated except where the distal and proximal electrodes are placed.
2. The cardiac electrocatheter as per claim 1, which is provided, besides the lumen for the electrode wires, with other multiple parallel lumens, with terminal and/or lateral eyelets, to insert ablation wires or fiberoptics, to apply suction and/or fluid infusion.
3. The cardiac electrocatheter as per claims 1 and 2, in which the distal electrode is hemispherically shaped and the proximal electrode is ring-shaped.
4. The cardiac electrocatheter as per claim 1 and 2, in which both the distal and proximal electrodes are ring-shaped.
5. The cardiac electrocatheter as per the preceding claims, in which the equivalent surface of the electrodes ranges between 5 and 15 mm^2.
6. The cardiac electrocatheter as per the preceding claims, in which the interelectrode distance ranges between 2 and 7 mm.
7. The cardiac electrocatheter as per the preceding claims in which the material of the electrodes is selected from the group comprising platinated platinum and amorphous carbon.
8. The cardiac electrocatheter as per the preceding claims, in which the wires connected to the electrodes are made in pure copper, the wires being about 200 μm in diameter.
9. The cardiac electrocatheter as per the previous claims, in which the catheter tube material is selected from the group comprising polyurethan, polyethylenterephtalate, polyethylene or polyvinylchloride.
10. The cardiac electrocatheter as per the previous claims, in which the catheter's size ranges between 1.67 and 2.60 mm (5 and 8 F).

FIG 1



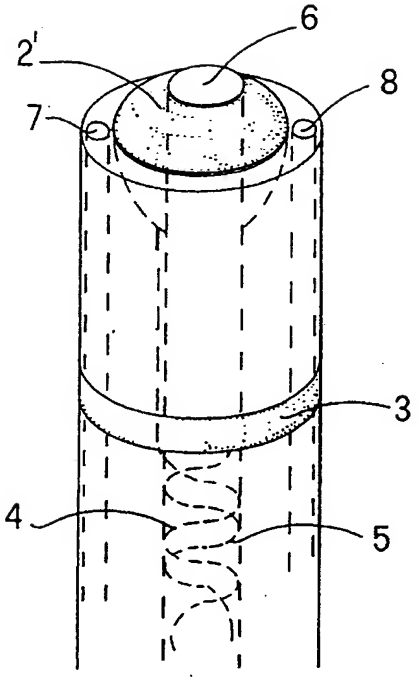


FIG 2

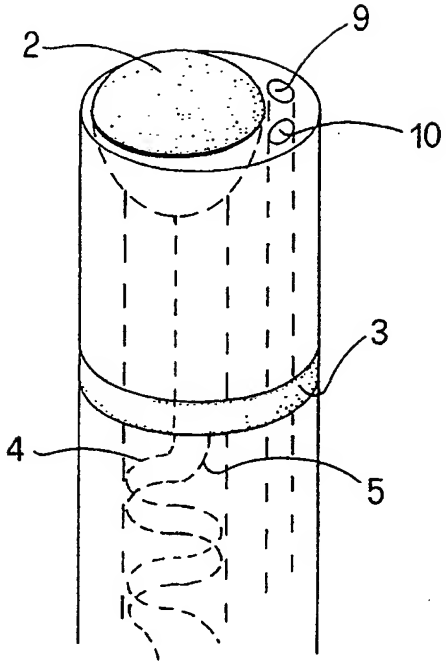


FIG 3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 89 83 0349

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	US-A-4559951 (R.W. DAHL ET AL.) * column 3, line 49 - column 4, line 7 * * column 5, line 19 - column 6, line 68 * * column 7, lines 25 - 52; figures * ---	1-3, 9	A61N1/05 A61B5/042
X	US-A-4682603 (M.R. FRANZ) * column 4, lines 13 - 35; figures 4, 5 * * column 5, line 55 - column 6, line 54 * ---	1-3, 6, 7, 10	
X	US-A-4847980 (F.X. WITKOWSKI) * column 3, lines 44 - 62; figures * * column 4, line 17 - column 5, line 64 * ---	1, 10	
A	US-B-535466 (R.L. CANNON) * column 1, line 56 - column 2, line 2 * * column 2, line 65 - column 4, line 10 * * figures * ---	1, 4, 7, 9	
A	US-A-4706681 (B. BREYER ET AL.) * column 1, line 41 - column 3, line 11; figures * ---	1, 4	
E	US-A-4860743 (G.S. ABELA) * column 5, line 1 - column 6, line 16 * * column 9, lines 3 - 56; figures * -----	1, 2, 4, 10	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A61N
A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	23 MARCH 1990	RIEB K.D.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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